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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/823,426	04/12/2004	Naweed Muhammad	524522001300	4034

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EXAMINER	
YOUNG, MICAH PAUL	
ART UNIT	PAPER NUMBER
1618	
MAIL DATE	DELIVERY MODE
12/28/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/823,426	MUHAMMAD ET AL.	
	Examiner	Art Unit	
	MICAH-PAUL YOUNG	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12/2/09*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *See Continuation Sheet* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,7,9-11,85,86,88-90,93,95,97-105,110,122-127,129-139 and 141-145* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims pending in the application are 1,7,9-11,85,86,88-90,93,95,97-105,110,122-127,129-139 and 141-145.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/2/09 has been entered.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 85, 86, 88, 89, 93, 98, 99, 101, 102, 134-136, and 142-145 are rejected under 35 U.S.C. 102(b) as being anticipated by LeHann (USPN 4,599,342 hereafter '342).

The '342 patent teaches a liquid formulation comprising a TRPV1 agonist, and a carrier formulation (abstract). The TRPV1 agonists include capsaicin and its derivatives and analogues (abstract, col. 4, lin. 10-12). The carrier formulation comprises propylene glycol, ethyl oleates and benzyl alcohol (col. 6, lin. 30-46, Example VI). The dosage form is liquid (col. 6, lin. 54-68). The formulation is administered in pre-packaged sterile syringes (Example V). The capsaicin concentration present in the liquid analgesic is present in amount of approximately 25% (Example VI). The carrier system comprises a combination of propylene glycol and benzyl

alcohol comprises up to about 75% of the liquid dosage form (Example VI). These disclosures render the claims anticipated.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1,7,9-11, 85, 86, 88-90, 93, 95, 97-105, 110, 122-127, 129-139, and 141-145 rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of LeHann (USPN 4,599,342 hereafter '342) in view of Jun (USPN 6,299,902 hereafter '902) and Beerse et al (USPN 5,968,539 hereafter '539).

As discussed above the '342 patent discloses a liquid formulation comprising capsaicin and a carrier formulation comprising a combination of alcohols. The references disclose a composition comprising about 25% capsaicin and the remainder of the formulation is the carrier formulation. The reference is silent to the inclusion of a local anesthetic or an emulsion dosage presentation.

The '902 patent discloses a liquid formulation comprising a local anesthetic such as lidocaine and capsaicin (abstract, col. 2, lin. 50-60). The topical formulation can be a microemulsion (claims). The formulation can be topical (col. 4, lin. 29-55). It would have been obvious to include a local anesthetic into the formulation of the '342 in order to reduce any initial pain upon injection or irritation. Further it would have been Obvious to formulate the composition as a microemulsion as seen in the '902 patent in order to improve the stability and storage properties of the formulation.

The '342 patent differs from the instant claims in that it is silent to a specific removal step or kit providing this feature, however any known removal method such as rinsing the applied area would be appropriate. A specific step would have been obvious to one of ordinary skill in the art in order to restore the skin to its original state. It would have been obvious to also rinse the applied area with a removal formulation that would leave the skin in its original state or better. This can be seen in the '539 patent.

The '539 patent discloses a mild rinse/off formulation comprising antimicrobial agents that continues to protect the skin against further infection (abstract). The mildest formulation that is most gentle to the skin comprises surfactants such as polyethylene glycol in a concentration from about 20-70% (col. 15, lin. 35-45). The liquid products can be applied to the forearm after it has been wet using a water tap from a standard basin, the formulation is applied and rinsed away in the basin (col. 21, lin. 55-col. 22, lin. 14). It would have been obvious to rinse the skin with the formulation of the '539 patent since it is mild and would also protect the skin against further bacterial infection.

Regarding the retention of the TRPV1 agonist in the skin, it is the position of the Examiner that such limitations are merely functional limitations inherent to the formulation, e.g., same compositions must have same properties. The method of the instant claims requires that a topical formulation comprising a TRPV1 agonist and a penetration enhancer in a specific surface area. The '342 patent teaches that the formulations are applied in at least this surface area in an effective method. The retention of the agonist is a function of the composition and since the compositions of the '342 and the instant claims are identical it follows that the '342 formulation must also act accordingly. It is the position of the Examiner that the formulation of the '342 would inherently remain in the skin of the desired duration in order to be fully effective.

Regarding the duration of the pain relief limitations, it is the position of the Examiner that such limitations are merely functional limitations that fall naturally from the practice of the claimed method. The prior art provides a method of delivering a TRPV1 compound to the skin in a comparable concentration, in combination with the same solvents, all combined into a similar form and applied to the same area. Since a compound and its properties cannot be separated, the practice of applying the liquid composition of the prior art comprising the same components of the instant claims will inherently provide pain relief for up to six months, depending on the pain and the individual.

Regarding the concentration of the capsaicin present in the formulation, it is the position of the Examiner that these limitations are the result of an optimization of ranges. This optimization would have been obvious to one of ordinary skill in the art. The combination discloses a topical formulation comprising a wide range of capsaicin concentrations from 0.25-25%. The carrier formulation makes up the remainder of the formulation. The carrier

formulation comprises the same polymers and alcohols of the instant claims. These general conditions are disclosed by the combination. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *See* In re Aller, 220 F.2d 454 105 USPQ 233, 235 (CCPA 1955).

With these things in mind it would have been obvious to include the anesthetics of the '902 patent into the formulation of the '342 patent in order to improve the pain relief properties of the formulation. It would have been obvious to process the combination as an microemulsion in order to improve the storage stability of the combined formulation. It would have been obvious to use the formulation in a kit or basin as described in the '539 in order to clean the skin and removes any of the harsh effects of the '342/902 combination. It would have been obvious to combine the prior art as such with an expected result of a stable method of treating pain.

Response to Arguments

Applicant's arguments with respect to claims 1, 7, 9-11, 85, 86, 88-90, 93, 95, 97-105, 110, 122-127, 129-139, and 141-145 have been considered but are moot in view of the new ground(s) of rejection.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 85, 86, 88-90, 93, 95, and 97-103 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 16, 17, 20, 21, 24, 25, 28, 39-45, 47, 50-54 and 60-63 of copending Application No. 11/411,328. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to pharmaceutical formulations comprising a TRPV1 agonists such as capsaicin in a topical formulation such as a gel, lotion or patch. The instant claims are more specific about including a penetration enhancer; however these components would be inherent to a gel, lotion or topical formulation meant to deliver agents to the skin. For these reasons the claims would act as obviating art over another.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICAH-PAUL YOUNG whose telephone number is (571)272-0608. The examiner can normally be reached on Monday-Friday 8:00-5:30; every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

/MICAH-PAUL YOUNG/
Examiner, Art Unit 1618